

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars:

1. Amendments and Support for Same

By the Response, claims 1 and 2 have been amended to more particularly point out and distinctly claim the subject matter of the invention. The amended features can be found in original claims 3, 8, and 9 as well as in, e.g., Figs. 1, 18, and 19, and paragraphs [0103]-[0104] and [0113] in the original specification. For example, the engagement portions are supported by features 140 and 141 or 2c and 4b in Figs. 1 and 19, while the guiding member alignment mark and tubular member alignment mark are shown in Fig. 18. No new matter has been added. Accordingly, claims 1-2, 4-8, and 10 are respectfully submitted for consideration. Approval and entry of the amendments are respectfully requested.

2. Rejection under 35 U.S.C. §102(b)

With respect to the rejection of claims 1-7 under 35 U.S.C. §102(b) as being anticipated by Fukuda (US 3,871,358), Applicant respectfully traverses the rejection at least for the reason that Fukuda fails to describe each and every limitation recited in the rejected claims.

As amended, independent claims 1 and 2 further clarify that when the guiding member engagement section is engaged with the tubular engagement member engagement section, or when the guiding member alignment mark and the tubular member alignment mark are aligned with each other, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member.

When using a supporting device for supporting insertion of a medical instrument into a human body, the guiding member is firstly inserted into the pharynx, and then the tubular member is inserted into the pharynx. If the tubular member is inserted too deeply, it may cause damage to the mucous membrane located at a deep portion/position of the digestive

organ. Therefore, when the tubular is inserted, not knowing the depth of insertion is a problem.

The presently claimed invention solves the above-mentioned problem. Particularly, according to Applicant's claimed invention, the guiding member has a smaller diameter than the tubular member, and, thus, the guiding member may be inserted easily into the tubular member. Further, for safely, desired insertion depth is easily determined by the use of the guiding member engagement section being engaged with the tubular member engagement section, or the guiding member alignment mark and the tubular member alignment mark being aligned with each other. As such, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member, and the claimed structure advantageously prevents the digestive organ end of the tubular member from being inserted too deeply. Accordingly, it is possible to carry out a safe operation.

Consequently, since each and every feature of the present claims is not taught (and is not inherent) in Fukuda, as is required by MPEP Chapter 2131 in order to establish anticipation, the rejection of claims 1-7, under 35 U.S.C. §102(b), as anticipated by Fukuda is improper.

In view of the amendment and arguments set forth above, Applicant respectfully requests reconsideration and withdrawal of the §102(b) rejection of claims 1-7.

3. Rejections under 35 U.S.C. §103(a)

With respect to the rejection of claims 8 and 10 under 35 U.S.C. §103(a) as being unpatentable over Fukuda in view of Turnbull (US 5,996,582), and to the rejection of claims 8 and 10 under 35 U.S.C. §103(a) as being unpatentable over Fukuda in view of Gomez (US 6,053,166), the rejection have been rendered moot by the amendment to claims 1 and 2 and the cancellation of claims 3, 8, and 9.

Notwithstanding the cancellation of claims 3, 8, and 9, Applicant respectfully traverses the rejection at least for the reason that Fukuda, Turnbull, and Gomez, combined or separately, fail to teach, disclose, or suggest all of the limitation recited in the rejected claims.

Turnbull is generally directed to a tracheal assembly having a tube 10 with a curve shaft 11 and a shield 20 that is slidable along the inside of the tube. The shield includes a

curved stiff rod 21 with a stop 22 which limits the extent of insertion of the shield into the tube. Applicant respectfully submits that the stop 22 of Turnbull is a part of the shield and stiff rod, which are being inserted as a tool that expands when the shield is inserted beyond the patient end of the tube to protect the posterior wall of the trachea during a tracheostomy procedure, while the guiding member (i.e., element 4 or 5 in Fig. 1) and the tubular member (i.e., 2 in Fig. 1) of the presently claimed invention are a part of a support device for supporting the insertion of a medical instrument into a human body.

Applicant respectfully asserts that the tube 10 of Turnbull may be equivalent to Applicant's tubular member (i.e., element 2 in Fig. 1). However, Turnbull does not teach, disclose, or suggest any feature equivalent to Applicant's guiding member (i.e., element 4 or 5 in Fig. 1), let alone a guiding member engagement section configured to be engaged with a tubular engagement member engagement section, or a guiding member alignment mark and a tubular member alignment mark configured to be aligned with each other when a digestive organ end of the guiding member is generally coincident with a digestive organ end of the tubular member, as recited in Applicant's amended claims 1 and 2. Hence, Turnbull and Fukuda, combined or separately, still fail to teach, disclose, or suggest all of the claimed features of the present invention.

With respect to Gomez, the Examiner contends that Gomez describe alignment marks, 22, 26, and 30. However, as clearly described in Gomez, elements 22, 26, and 30 are introduction segments that provide a modification of curvature of intubation tube 80. Applicant respectfully submits that there is no teaching, disclosure, or suggestion in Gomez of a guiding member engagement section configured to be engaged with a tubular engagement member engagement section, or a guiding member alignment mark and a tubular member alignment mark configured to be aligned with each other when a digestive organ end of the guiding member is generally coincident with a digestive organ end of the tubular member, as recited in Applicant's amended claims 1 and 2. Hence, Gomez and Fukuda, combined or separately, still fail to teach, disclose, or suggest all of the claimed features of the present invention.

The requirements for establishing a *prima facie* case of obviousness, as detailed in MPEP § 2143 - 2143.03 (pages 2100-122 - 2100-136), are: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference to combine the teachings;

second, there must be a reasonable expectation of success; and, finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations.

Further, according to MPEP §2141(I), Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Moreover, according to MPEP §2141(II), when applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

In view of the amendment and arguments set forth above, Applicant respectfully requests the Examiner to follow tenets A-D in relying on Fukuda, Gomez, and Turnbull in the rejection of claims 8-10. Further, Applicant respectfully requests reconsideration and withdrawal of the §103(a) rejection of claims 8-10.

4. Conclusion

In view of the amendments to the claims, and in further view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is requested that claims 1-2, 4-7, and 10 be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the Applicant's representative, the Examiner is invited to contact the undersigned at the numbers shown.

Further, while no fees are believed to be due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4525.

Respectfully submitted,

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